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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,104	03/19/2007	Valerie Arranz	62745.000021	6158

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EXAMINER
DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
1645	

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09/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,104	ARRANZ, VALERIE	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Lack of Unity & Species Election

1) Claims 1-13 are under prosecution.

2) As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

3) As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

4) Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-9, drawn to the use of a peptide for the preparation of pharmaceutical composition for treating a Gram negative bacterial infection.

II. Claims 10 and 11, drawn to an antibacterial composition comprising at least a peptide and an antibacterial compound.

III. Claims 12 and 13, drawn to a product of formula I comprising the residue of a peptide, the residue of an antibacterial compound, and a spacer arm.

5) Inventions I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of the first claimed invention is the use of a peptide such as SEQ ID NO: 1 for the preparation of pharmaceutical composition for treating a Gram negative bacterial infection. However, such an invention was already disclosed in the art at the time of the invention. For example, Avrameas *et al.* (WO 01/64738 A2 – Applicants' IDS) disclosed the use of their SEQ ID NO: 27 peptide comprising the instantly recited SEQ ID NO: 1 for transferring or transporting *in vivo* a substance of interest, particularly a drug, to cells, for preparation of a pharmaceutical composition aimed at treating Gram negative bacterial infections. See the entire document including claim 53 and page 92; and the sequence alignment and the disclosure below:

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AAG67718
ID   AAG67718 standard; peptide; 18 AA.
AC   AAG67718;
DT   10-DEC-2001  (first entry)
DE   D-form peptide of insulin-like growth factor binding protein.
KW   heparin; aminoglycan; intracytoplasmic delivery; intranuclear delivery;
KW   protein therapy; gene therapy; viral infection; bacterial infection;
KW   cancer; metastasis; apoptosis; degenerative disease; ischemia;
KW   pathological neoangiogenesis; insulin-like growth factor binding protein.
OS   Synthetic.
OS   Homo sapiens.
FH   Key             Location/Qualifiers
FT   Misc-difference 1. .18
FT   /note= "all residues are D-form"
PN   WO200164738-A2.
PD   07-SEP-2001.
PF   01-MAR-2001; 2001WO-FR000613.
PR   01-MAR-2000; 2000FR-00002621.
PA   (DIAT-) DIATOS SA.
PI   Avrameas E,  Ternynck T;
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DR   WPI; 2001-596767/67.
PT   Amino acid sequences for intracellular transport of compounds, useful
PT   e.g. for protein or gene therapy, react with aminoglycans and are
PT   actively transported to cytoplasm or nucleus.
PS   Disclosure; Page 134; 139pp; French.
CC   AAG67713-30 represent peptides whose capacity to react with and bind DNA
CC   and various heparin proteoglycans was tested. Peptides which had the
CC   ability to bind these were determined to be peptides of the invention.
CC   The specification describes peptides that facilitate penetration of a
CC   substance of interest into the inside of a cell and/or its nucleus. The
CC   peptide of the invention can react in vivo with aminoglycans, and is
CC   derived from proteins of human origin. Using the peptide as a vector
CC   avoids risks/toxicity associated with viral vectors, electroporation or
CC   other transfer methods. It is actively transported into cells, and by
CC   varying its amino acid composition, either intracytoplasmic or
CC   intranuclear delivery is achieved. The peptides of the invention are
CC   used, in vivo or in vitro, for transferring substances of interest
CC   (particularly nucleic acid, protein, drug, antigen or antibody) to cells,
CC   e.g. for preparation of biological, pharmaceutical, cosmetic,
CC   nutritional, diagnostic or tracer compositions, e.g. for protein or gene
CC   therapy. Typical applications are treatment or prevention of viral and
CC   bacterial infections, cancer, metastasis, apoptosis (in degenerative
CC   diseases and ischemia) and pathological neoangiogenesis
SQ   Sequence 18 AA;

  Query Match             100.0%;  Score 78;  DB 1;  Length 18;
  Best Local Similarity   100.0%;  Pred. No. 0.0021;
  Matches   16;  Conservative  0;  Mismatches   0;  Indels  0;  Gaps  0.

Qy          1 RKKRRRESRKKRRRES 16
              ||||||||||||||||
Db          3 RKKRRRESRKKRRRES 18
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Thus, the special technical of the first claimed invention is taught by the prior art, and therefore does not define over the prior art. Although the first claimed use of invention I and the product of invention II, is a permitted combination under PCT Rule 13.2, in the instant case, since the former is already disclosed in the art, the special technical feature is not a unifying feature. Technically, the absence of special technical feature permits the separation of the method of using or making the product from the product itself. The special technical feature of the subsequently claimed invention is delineated above. The subsequently claimed product of the specific formula of invention III does not share significant common structure with the product of invention II.

6) The Office has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process

invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.* Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7) This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, the species lack the same or corresponding special technical features as these species do not share a *significant* common structure, function and/or source.

Anti-bacterial compound species (see claim 7):

(a) Erythromycin;

(b) Clarythromycin;

(c) Azithromycin; and

(d) Telithromycin.

Claims 1-6, 8 and 9 are generic.

8) Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143)

and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

9) The election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record, showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C § 103(a) of the other invention.

10) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

11) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA and CANADA) or 571-272-1000.

12) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to

Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached on (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

September, 2009